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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,585	07/25/2005	John W. Morris	285-323 PCT US	2545

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DORSEY & WHITNEY LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
SUITE 1500  
50 SOUTH SIXTH STREET  
MINNEAPOLIS, MN 55402-1498

EXAMINER
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SINGH, ANOOP KUMAR

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,585	<b>Applicant(s)</b> MORRIS ET AL.	
	<b>Examiner</b> CELINE X. QIAN	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-25 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,10,24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1, 2, 4-25 are pending in the application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/29/08 has been entered.

#### ***Response to Amendment***

Claims 8, 9, 11-23 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1, 2, 4-7, 10, 24 and 25 are currently under examination.

The rejection of claims 1, 2, 4-7, 10, 24 and 25 under 35 U.S.C. 112 1<sup>st</sup> paragraph has been withdrawn.

The amendment to the specification has been entered.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall

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have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 7, 10, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowd et al (US 5507813).

Dowd et al. disclose a method for preparing the shaped osteogenic materials by using a quantity of elongate bone particles, preferably those that have been demineralized, slurried in a suitable liquid, e.g., water, organic protic solvent, aqueous solution such as physiological saline, etc., and optionally containing one or more biocompatible ingredients such as adhesives, fillers, plasticizers, flexibilizing agents, biostatic/biocidal agents, surface active agents, medically/surgically useful substances, etc., is applied to a form such as a flat sheet, mesh screen or three-dimensional mold and excess liquid is removed, e.g., by being drained away. The wet demineralized bone particles are then subject to lyophilization in accordance with procedures and conditions that are well known in the art, e.g., a shelf temperature of from about -20.degree. to about -35.degree. C., a vacuum of from about 150 to about 100 mTorr for a time of from about 4 to about 48 hours depending on the mass. In an alternative embodiment herein, the entangled mass of bone particles can be subjected to a compressive force, e.g., of up to about 100 psi, during and/or after the wet-laying step and/or while the drained but still wet shaped article is being dried. The resulting shaped material is rigid and relatively strong when dry and flexible and pliable when wetted or hydrated (see description of the preferred embodiments, 10<sup>th</sup> paragraph). Dowd et al. further disclose that at the site of implantation, the shaped article can be employed in the dry state or, where site conformation is desired, in the hydrated state. The dry or hydrated article can be cut or

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sized if need be to conform to a site being repaired. The disclosure of Dowd et al. teaches every step of the claimed invention. Therefore, Dowd et al. anticipates the claimed invention.

Claims 1, 2, 4-7 and 24 rejected under 35 U.S.C. 102(e) as being anticipated by Boyce et al. (US 6863694)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Boyce et al. disclose a method of making osteogenic osteoimplant by using bone derived elements. Boyce et al. disclose that the bone derived elements may be at least partially demineralized (see for example, col.7, 3<sup>rd</sup> paragraph, lines 1-3). Boyce et al. also disclose that the bone derived elements is mixed with a fluid carrier, such as water or glycerol, and additional optional ingredients (see col. 12, last paragraph, and col. 13, 1<sup>st</sup> and 2<sup>nd</sup> paragraph) to form a dough-like composition. Boyce et al. further disclose that this composition may subject to mechanical shaping, and then subdivided into sections suitable for implant (see col. 14, lines 23-26, lines 53-57, and col. 16, lines 63-65). Boyce et al. also disclose that this composition is preferably dehydrated, e.g. lyophilized, and/or frozen prior to packaging for use (see col. 14, lines 62-67). The disclosure of Boyce et al. anticipates the claimed method because it discloses every step of the method.

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Claims 1, 2, 4, 5, 10, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Sherwood et al (US 6454811B1).

Sherwood et al. disclose a method of producing bone and polymer coacervate by mixing bone particles with polymer solution to form a uniformly dispersed solution (see col.19, lines 35-42). Sherwood et al. disclose that isopropanol is added to this solution to harden the polymer and produce coacervate, wherein the solid is collected, filtered, and dried under vacuum. Then the composition is milled to produce bone particles (see col. 19, lines 47-52). Sherwood et al. discloses the instantly claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /  
Primary Examiner, Art Unit 1636